OCT 30 2009

DEVICE DESCRIPTION: The BAXJECT II Hi-Flow Needleless Transfer Device is a double-sided needleless transfer device designed for transferring and mixing of drugs contained in two vials into a syringe.

STATEMENT OF INTENDED USE: The BAXJECT II Hi-Flow Needleless Transfer Device is intended for transferring and mixing of drugs contained in two vials into a syringe.

TECHNOLOGICAL CHARACTERISTICS: The BAXJECT II Hi-Flow Needleless Transfer Device is substantially equivalent to the predicate devices with regard to technological characteristics, performance, and intended use.

ASSESSMENT OF NONCLINICAL DATA: Baxter Healthcare Corporation conducts risk analysis according to the requirements of ISO 14971:2007 Medical Devices-Application of Risk Management to Medical Devices.

The device continues to meet the same material testing standards and sterilization process standards as the predicate devices. Device verification testing of performance has been verified through functional and biocompatibility testing.

CONCLUSIONS: The BAXJECT II Hi-Flow Needleless Transfer Device is substantially equivalent to the predicate device. Testing against established standards and guidelines for its intended use demonstrate that the proposed device is as safe and effective as the predicate device.

K092318 p. 2 of 2

5. 510(k) SUMMARY

DATE: July 20, 2009

OWNER

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015

CONTACT PERSON:

Valerie Followell
Manager, Global Regulatory Affairs
1620 Waukegan Road, MPGR-AL
McGaw Park, IL 60085
Telephone: 847-270-4375
Fax: 847-785-5116
Email: valerie_followell@baxter.com

DEVICE NAME:

Trade name: BAXJECT II Hi-Flow Needleless Transfer Device
Common name: Set, IV Fluid Transfer
Classification: Intravascular administration set, Vial adapter
Class: Class II
Product Code: LHI

PREDICATE DEVICE(S): Previously cleared 510(k) for Baxter Healthcare Corporation, BAXJECT II Needleless Transfer Device

Predicate 510(k)	Device Name	Indication	Clearance date	Company
K042410	BAXJECT II Needleless Transfer Device	Transfer and mixing of drugs contained in two vials into a syringe	10/08/2004	Baxter Healthcare Corporation
K001831	Needleless Transfer Device	Transfer and mixing of drugs contained in two vials into a syringe	07/11/2000	MediMop Medical Products

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Baxter Healthcare Corporation
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

OCT 3 0 2009

Re: K092318
Trade/Device Name: BAXJECT II Hi-Flow Needleless Transfer Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: October 15, 2009
Received: October 16, 2009

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K092318

Device Name: BAXJECT II Hi-Flow Needleless Transfer Device

Indication(s) for Use:

The BAXJECT II Hi-Flow Needleless Transfer Device is intended for transferring and mixing of drugs contained in two vials into a syringe.

Prescription Use: ☑ 21 CFR 801 Subpart D

AND/OR

Over-the-Counter Use: ☐ 21 CFR 801 Subpart C

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092318